DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 18, 2015

Shanghai Jinxiang Latex Products Co., Ltd.
c/o Mr. Chu Xiaoan
Beijing Easy-link Company
Building 41, Room F302, Jing Cheng Ya Ju,
Courtyard 6 of Southern Dou Ge Zhuang
Chaoyang District, Beijing, 100121
CHINA

Re: K142992
Trade/Device Name: TULIP Natural Rubber Latex Surgeon's Glove (Powdered)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's glove
Regulatory Class: I
Product Code: KGO
Dated: February 1, 2015
Received: February 19, 2015

Dear Mr. Xiaoan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142992

Device Name
TULIP Natural Rubber Latex Surgeon's Glove (Powdered)

Indications for Use *(Describe)*
A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section C 510(k) Summary

510(K) Summary

The assigned 510(k) number is: K142992

Application Correspondent

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Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Shanghai Jinxiang Latex Products Co., Ltd.
Submitter's address :	No.36 Leizhou Road, Xinghuo Development Area, Fengxian District, Shanghai 201419, P.R. China
Phone number :	86-21-57127613
Fax number :	86-21-55092607
Name of contact person:	Ms.Wang Xiaoyan
Date of preparation :	2015-03-18

2.0 Name of the Device

Device Name:	Natural Rubber Latex Surgeon's Gloves (Powdered)
Proprietary/Trade name:	TULIP Natural Rubber Latex Surgeon's Glove (Powdered)
Common Name:	Surgical Gloves
Classification Name:	Surgeon's glove
Device Classification:	I
Regulation Number:	21 CFR 878.4460
Panel:	General& Plastic Surgery
Product Code:	KGO

3.0 Predicate device

510(K) Number:	K063757
Device Name:	Motex Powder-Free Surgical Gloves & Powdered Latex Surgical Gloves
Company name:	SHANGHAI MOTEX HEALTHCARE CO., LTD.

4.0 Device Description:

The proposed device. Latex Surgeon's Gloves Powdered is a sterilized and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination

The proposed device is made of natural rubber latex, per standard ASTM D3577-09^{e1}, the rubber surgical gloves classification is:
"Type I - gloves compounded primarily from natural rubber latex"

The proposed device is Powdered Latex Surgeon's Gloves, and variations of different size. All variations share the same color, creamy white.

The proposed device is provided Gamma radiation sterilized to achieve the Sterility Assurance Level (SAL) of 10-6 and place in a sterility maintenance package to ensure a shelf life of 3 years.

5.0 Device Intended Use (Indication for use):

A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

6.0 Summary of the Technological Characteristics of the Device:

The sterile Latex Surgeon's Gloves Powdered is summarized with the following technological characteristics compared to ASTM or equivalent standard.

Table I Technological Characteristics

Characteristics	**Standard**		**Device performance**	
Dimension	ASTM standard D 3577-09^{e1}			
--Palm width	Size	(mm)	(mm)	
	6	76±6	73-80	
	6½	83±6	80-85	
	7	89±6	86-90	
	7½	95±6	92-98	
	8	102±6	100-104	
	8½	108±6	106-111	
--Length	≥265mm min		273-297	
--Thickness fingertip	≥0.10mm min		0.22-0.31	
--Thickness palm	≥0.10mm min		0.22-0.30	
--Thickness cuff	≥0.10mm min		0.20-0.30	
Physical Properties	ASTM standard D 3577-09^{e1}			
	Before Aging	After Aging	Before Aging	After Aging
--Tensile Strength	24Mpa	18Mpa (min)	26-30Mpa	21-25Mpa (min)
--Stress at 500% elongation	5.5Mpa(MAX)	--	3.5-4.0Mpa	--
--Ultimate elongation	750%	560% (min)	800-890%	650-780%
Freedom from pinholes	21 CFR 800.20		Passed Standard Acceptance Criteria	
Powder Amount	D6124-06(Reaffirmation 2011)		Meets ≤15 mg/dm2	
Protein Level	ASTM standard D 5712-10		Meets ≤200 μg/dm^2	
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: 2010-08-01		Passes Not a Primary Skin Irritation	

	Dermal sensitization in the guinea pig ISO 10993-10: 2010-08-01	Passes Not a Dermal sensitization
Sterilization Validation	ISO 11137-1:2006	Sterility Assurance Level (SAL) of 10^{-6}.

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data:

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D3577-09e1. Standard Specification for Rubber Surgical Gloves.
ASTM D5151 -06 (Reapproved 2011) Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (Reaffirmation 2011) Standard Test Method for Residual Powder on Medical Gloves.
ASTM D5712-10 Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method.
ASTM D7160-05 (Reapproved 2010) standard practice for determination of expiration dating for medical gloves.
ASTM F 1929-98 (2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible barrier Materials.
ASTM D3078-02 (Reapproved 2013) standard test method for determination of leaks in flexible packaging by bubble emission.
ISO 10993-10:2010 Biological evaluation of medical devices - Part 10 ： Tests for irritation and skin sensitization.
ISO 11137-2:2006 Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose

The performance test data of the nonclinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data was not including in this submission.

9.0 Substantial Equivalence Comparison:

Table II Substantially Equivalent Comparison

Item	Proposed Device	Predicate Device (k063757)
Product Code	KGO	Same
Regulation No.	21 CFR 878.4460	Same
Class	I	Same
Intended Use	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	Similar
Powdered	Only Powdered(no Powdered free)	Powdered and Powdered-free
Classification per ASTM D3577	Type I - gloves compounded primarily from natural	Same

Dimensions	Size 6, 6.5, 7, 7.5, 8, 8.5, Dimensions comply with ASTM D3577	Similar
Physical properties	Comply with ASTM D3577	Same
Freedom from Holes	Comply with ASTM D3577 and ASTM D5151	Same
Powder Content	Comply with ASTM D3577 and ASTM D6124	Same
Protein Content	Comply with ASTM D3577 and ASTM D5712	Same
Biocompatibility	Comply with ISO 10993-10	Same
Sterilization	Gamma radiation,SAL:10^{-6}	Same
Label and Labeling	Meet FDA's Requirements	Same

10.0 Conclusion:

Based on the information summarized above, the subject device, TULIP Natural Rubber Latex Surgeon's Glove (Powdered), is determined to be Substantially Equivalent (SE) to the predicate device, Motex Powder-Free Surgical Gloves & Powdered Latex Surgical Gloves (K063757).